APR 2 4 2003

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510(k) Summary

NAME OF SPONSOR:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(K) CONTACT:	**Karla A. Ham** Senior Regulatory Associate Phone: (574) 371-4925 FAX: (574) 371-4987
TRADE NAME:	**DePuy Solution System Hip Prosthesis**
COMMON NAME:	Cemented or cementless porous-coated hip prosthesis
CLASSIFICATION:	**Class II** Device per 21 CFR 888.3358: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
DEVICE PRODUCT CODE:	**87LPH**
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Vision Solution Hip Prosthesis, K953703 DePuy AML Hip Prosthesis, K012364

DEVICE DESCRIPTION:
The DePuy Solution System Hip Prosthesis is manufactured from ASTM F-75 Cobalt Chromium-Molybdenum alloy and has a sintered cobalt-chrome-molybdenum alloy bead porous coating (Porocoat®) applied to the stem. The porous coating is applied to the entire stem with the exception of the polished neck and tapered stem tip region. The DePuy Solution System Hip Prosthesis is a single use device.

INTENDED USE AND INDICATIONS:
The DePuy Solution System Hip Prosthesis is intended for use in total hip arthroplasty in either a cementless (by biological tissue ingrowth into the porous coating) or cemented application (in which the porous coating serves as a means to augment the fixation of the prosthesis to the bone cement). Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Total hip replacement is indicated in the following conditions:

1. Severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthro-plasty, or total hip replacement.
5. Certain cases of ankylosis.

510(k) Summary (cont.)

BASIS OF SUBSTANTIAL EQUIVALENCE:
Based on similarities of design, same materials, identical sterilization processes, and the same intended use, DePuy believes that the modified DePuy Solution System Hip Prosthesis is substantially equivalent to the previously cleared Vision Solution Hip Prosthesis (K953703) and the DePuy AML Hip Prosthesis (K012364).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2003

Ms. Karla A. Ham
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581

Re: K030979
Trade/Device Name: DePuy Solution System® Hip Prosthesis
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: March 25, 2003
Received: March 28, 2003

Dear Ms. Ham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030979

Device Name: DePuy Solution System® Hip Prosthesis

Indications for Use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

The DePuy Solution System Hip System is indicated for cementless use and fixation by biological tissue ingrowth into the porous coating as well as cemented use and fixation in which the porous coating serves as a means to augment the fixation of the prosthesis to the bone cement.

Concurrence of CDRH, Office of Device Evaluation

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030979

Prescription Use Y (Per 21 CFR 801.109) OR Over-The-Counter Use N